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10/624,150	07/17/2003	Robert W. Childers	DI-5828	5656

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EXAMINER	
SCHELL, LAURA C	

ART UNIT	PAPER NUMBER
3767	

NOTIFICATION DATE	DELIVERY MODE
05/13/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/624,150	CHILDERS ET AL.	
	Examiner	Art Unit	
	LAURA C. SCHELL	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 7, 13, 24 and 29 and consequently all dependent claims are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In reference to claim 1, the phrase "consisting of" is being considered new matter as the Examiner can not find support in the specification or drawings for a fluid circuit containing *only*: a fluid loop, supply of dialysate, chamber, cleaning device, cycler and discharge fluid path. The examiner notes that Applicant has pointed to Fig. 3a and paragraphs [0080]-[0082] and [0088]-[0091] for support, however, upon reviewing the paragraphs and Fig. 3a, the examiner still finds extra elements which are not claimed in the "consisting of" clause in claim 1. For example the extra elements include an extra cycler (there are two cyclers 44), the variable volume chamber (49) and the back pressure regulator (59), all of which do not appear in the consisting of clause in claim 1. Also, the discharge fluid pathway is missing from Fig. 3a and is not found within

paragraphs [0080]-[0082] and [0088]-[0091]. Also, it is unclear if Applicant is interpreting the top pump 44 to be the cycler, as the cycler in the claim must pump the dialysate into the circuit as well as circulate it. From Fig. 3a it appears that 44 is capable of circulating dialysate but it does not appear capable of pumping dialysate into the circuit as it would need to be attached to a source of dialysate. Furthermore, it is also unclear if element 44 can be interpreted as a cycler, as Applicant's specification only mentions a cycler in relation to Figs. 4a, 4b, 5a and 5b.

In reference to claims 7 and 29, the phrase “ion exchange resin” is being considered new matter. While the examiner has found support in the specification for the cleaning device comprising sorbent material (paragraph [0083]), the examiner has not found support for any resin. The examiner agrees, upon reviewing Applicant's arguments that there is support in the specification for an ion exchange occurring, however the specification does not provide support for it occurring due to a resin. The examiner is therefore suggesting language along the lines of “wherein the cleaning device is capable of ion exchange” which has support in paragraph [0087].

In reference to claim 13, the phrase “consisting of” is being considered new matter as the Examiner can not find support in the specification or drawings for a fluid circuit containing *only*: a fluid loop, supply of dialysate, chamber, cycler and discharge fluid path. The examiner notes that Applicant has pointed to Fig. 3a and paragraphs [0080]-[0082] and [0088]-[0091] for support, however, upon reviewing the paragraphs and Fig. 3a, the examiner still finds extra elements which are not claimed in the “consisting of” clause in claim 1. For example the extra elements include an extra

cycler (there are two cyclers 44), the variable volume chamber (49) and the back pressure regulator (59), all of which do not appear in the consisting of clause in claim 1. Also, the discharge fluid pathway is missing from Fig. 3a and is not found within paragraphs [0080]-[0082] and [0088]-[0091]. Also, it is unclear if Applicant is interpreting the top pump 44 to be the cycler, as the cycler in the claim must pump the dialysate into the circuit as well as circulate it. From Fig. 3a it appears that 44 is capable of circulating dialysate but it does not appear capable of pumping dialysate into the circuit as it would need to be attached to a source of dialysate. Furthermore, it is also unclear if element 44 can be interpreted as a cycler, as Applicant's specification only mentions a cycler in relation to Figs. 4a, 4b, 5a and 5b.

In reference to claim 24, the phrase “consisting of” is being considered new matter as the Examiner can not find support in the specification or drawings for a fluid circuit containing *only*: a fluid loop, supply of dialysate, cycler, cleaning device and discharge fluid path. The examiner notes that Applicant has pointed to Fig. 3a and paragraphs [0080]-[0082] and [0088]-[0091] for support, however, upon reviewing the paragraphs and Fig. 3a, the examiner still finds extra elements which are not claimed in the “consisting of” clause in claim 1. For example the extra elements include an extra cycler (there are two cyclers 44), the variable volume chamber (49) and the back pressure regulator (59), all of which do not appear in the consisting of clause in claim 1. Also, the discharge fluid pathway is missing from Fig. 3a and is not found within paragraphs [0080]-[0082] and [0088]-[0091]. Also, it is unclear if Applicant is interpreting the top pump 44 to be the cycler, as the cycler in the claim must pump the

dialysate into the circuit as well as circulate it. From Fig. 3a it appears that 44 is capable of circulating dialysate but it does not appear capable of pumping dialysate into the circuit as it would need to be attached to a source of dialysate. Furthermore, it is also unclear if element 44 can be interpreted as a cycler, as Applicant's specification only mentions a cycler in relation to Figs. 4a, 4b, 5a and 5b.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 2 and 5-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Treu et al. (US Patent No. 6254567) in view of Roberts et al. ("Innovative Peritoneal Dialysis: Flow-Thru and Dialysate Regeneration"). Treu discloses the device substantially as claimed including a system for providing peritoneal dialysis to a patient (Fig. 2), the system comprising: a catheter having an inflow lumen and an outflow lumen

(col. 6, lines 3-6 disclose that a dual lumen catheter may be used) in communication with the patient's peritoneal cavity (20); and a fluid circuit (Fig. 2) in fluid communication with the catheter, the fluid circuit consisting of: a fluid loop (10), the fluid loop configured to circulate dialysate into, through and out of a peritoneal cavity of the patient (the dialysate follows the path through the loop 10 multiple times as it is regenerated); a supply of dialysate coupled to the fluid circuit; at least one of a chamber coupled to the fluid loop through which the dialysate can be fed at a feed rate into the fluid loop (88 allows the dialysate to be fed back into the fluid loop via the actions of the valves), and a cleaning device (22) coupled to the fluid loop via a cleaning fluid path (the path includes entering the cleaning device via 32, flowing through the cleaning device and re-entering the fluid loop via 34) wherein the dialysate can be fed into the cleaning fluid path and cleaned at a cleaning rate prior to reintroduction into the fluid loop (please note that the claim language does not require that the cleaning rate be a specific rate relative to any other rate claimed, therefore the rate at which the fluid flows through the cleaning device is being interpreted as the cleaning rate); a cycler (12) that pumps the dialysate into the fluid circuit at a feed rate and circulates the dialysate at a circulation rate along the fluid loop to remove a therapeutic effective amount of solutes and excess water from the patient (please note that the claim language does not require that the feed rate and circulation rates be specific rates as compared to other rates in the claim); and a discharge fluid path (fluid path leading to 46) coupled to the fluid loop through which the dialysate is drained from the fluid circuit at a discharge rate. Treu, however, discloses components which are not claimed: pressure sensors (76 and 78) and valves 80 and

92. Treu later discloses, however, that other arrangements can be used such that inline pressure sensors are not necessary (col. 10, lines 11-12 and 20-21). Also, Treu further discloses that valves 80 and 92 as well as the pressure sensors 76 and 78 are part of the cycler (col. 6, lines 33-35 and 42-45), and Applicant's specification discloses that a cycler can include other elements besides just a pump, such as valves, for example (Applicant's specification paragraph [0021]). Therefore, the pressure sensors and valves can be interpreted as part of the cycler, which is an element claimed by Applicant in each independent claims. Treu, however, does not disclose that the fluid is drained at a discharge rate that is less than the circulation rate allowing the dialysate to be circulated a plurality of times along the fluid loop prior to discharge. Roberts, however, discloses a similar fluid loop in which the fluid is drained at a rate less than the circulation rate thus allowing the fluid to circulate a plurality of times along the fluid loop prior to being drained (col. 1, second paragraph on page 377 discloses that the inflow and outflow of dialysate are set to equal each other, at a rate of 30 ml/min and that the fluid in the peritoneum is at a higher circulation rate; also see paragraph 2, col. 2 of page 374 which discloses the same author cited as using circulation rate of 200 ml/min and inflow and outflow rates of 36 ml/min thus allowing the fluid in the peritoneum to circulate several times before being discharged.). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Treu such that pressure sensors are not used in the fluid circuit as taught by Treu, and modify True with the lower discharge rate as taught by Roberts, in order to allow the fluid to be used the maximum amount possible before being drained as waste. Also it is

the examiner's position that it would be obvious to use the teaching by Roberts to drain the fluid at a rate that is slower than the circulation rate, as this is only a change to the rates at which the system/fluid flow is operated, and constitutes only finding an optimum value of a result effective variable which is routine in the art.

In reference to claim 2, Treu discloses at least one pressure sensor coupled to the fluid circuit for sensing a pressure (76, 78).

In reference to claim 5, Treu discloses that the cycler comprises two pumps (Fig. 5 discloses an embodiment in which there are two pumps (70 and 100)).

In reference to claim 6, Treu discloses that the cleaning device contains sorbents for adsorbing at least one of urea, phosphate and creatinine (col. 1 lines 25-26 disclose that the waste products removed by the cleaning device include urea and creatinine).

In reference to claim 7, Treu discloses that the cleaning device contains an ion exchange resin (col. 1, line 24).

In reference to claim 8, Treu discloses that the cleaning device contains at least one electrolyte for addition to the dialysate (col. 8, lines 58-61).

In reference to claim 9, Treu discloses that the cleaning device contains at least three layers (col. 4, lines 24-41).

In reference to claim 10, Treu discloses the chamber (88) allowing the fluid loop to accommodate a variable increase in the dialysate during treatment (Fig. 2).

In reference to claim 11, Roberts discloses that the increase is due to an addition of ultrafiltrate to the fluid loop (paragraph 2, col. 2 of page 374).

In reference to claim 12, Treu discloses at least one valve connecting the catheter to the fluid circuit (80 and 92 in Fig. 2).

Claims 13, 14, 16-20, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Treu et al. (US Patent No. 6254567) in view of Roberts et al. ("Innovative Peritoneal Dialysis: Flow-Thru and Dialysate Regeneration"). Treu discloses the device substantially as claimed including a system for providing peritoneal dialysis to a patient (Fig. 2), the system comprising: a catheter having an inflow lumen and an outflow lumen (Fig. 2 discloses an embodiment which uses a double lumen catheter 18; col. 6, lines 3-6 disclose that a dual lumen catheter may be used) in communication with the patient's peritoneal cavity (20); and a fluid circuit (Fig. 2) in fluid communication with the catheter, the fluid circuit consisting of: a fluid loop (10), the fluid loop configured to circulate dialysate into, through and out of a peritoneal cavity of the patient (the dialysate follows the path through the loop 10 multiple times as it is regenerated) via only a single loop of the fluid loop (Fig. 2 discloses that this can be accomplished by passing through the loop 10 once); a supply of dialysate; a chamber coupled to the fluid loop through which the dialysate can be fed at a feed rate into the fluid loop (88 allows the dialysate to be fed back into the fluid loop via the actions of the valves); a cycler (12) that pumps the dialysate into the fluid circuit at a feed rate and circulates the dialysate at a circulation rate along the fluid loop to remove a therapeutic effective amount of solutes and excess water from the patient (please note that the

claim language does not require that the feed rate and circulation rates be specific rates as compared to other rates in the claim); and a discharge fluid path (fluid path leading to 46) coupled to the fluid loop through which the dialysate is drained from the fluid circuit at a discharge rate. Treu, however, discloses components which are not claimed: pressure sensors (76 and 78) and valves 80 and 92. Treu later discloses, however, that other arrangements can be used such that inline pressure sensors are not necessary (col. 10, lines 11-12 and 20-21). Also, Treu further discloses that valves 80 and 92 as well as the pressure sensors 76 and 78 are part of the cycler (col. 6, lines 33-35 and 42-45), and Applicant's specification discloses that a cycler can include other elements besides just a pump, such as valves, for example (Applicant's specification paragraph [0021]). Therefore, the pressure sensors and valves can be interpreted as part of the cycler, which is an element claimed by Applicant in each independent claims. Treu, however, does not disclose that the fluid is drained at a discharge rate that is less than the circulation rate allowing the dialysate to be circulated a plurality of times along the fluid loop prior to discharge. Roberts, however, discloses a similar fluid loop in which the fluid is drained at a rate less than the circulation rate thus allowing the fluid to circulate a plurality of times along the fluid loop prior to being drained (col. 1, second paragraph on page 377 discloses that the inflow and outflow of dialysate are set to equal each other, at a rate of 30 ml/min and that the fluid in the peritoneum is at a higher circulation rate; also see paragraph 2, col. 2 of page 374 which discloses the same author cited as using circulation rate of 200 ml/min and inflow and outflow rates of 36 ml/min thus allowing the fluid in the peritoneum to circulate several times before being discharged.).

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Treu such that pressure sensors are not used in the fluid circuit as taught by Treu, and modified Treu with the lower discharge rate as taught by Roberts, in order to allow the fluid to be used the maximum amount possible before being drained as waste. Also it is the examiner's position that it would be obvious to use the teaching by Roberts to drain the fluid at a rate that is slower than the circulation rate, as this is only a change to the rates at which the system/fluid flow is operated, and constitutes only finding an optimum value of a result effective variable which is routine in the art.

In reference to claim 14, Roberts discloses that the supply of dialysate contains about 25 liters or less of dialysate (Fig. 12, which is circuit that modified circuit of paragraph 2 is based on, uses 20 L of dialysate, which is less than 25 L).

In reference to claim 16, Roberts discloses that the circulation rate is about 300 ml/min or less (Roberts discloses in paragraph 1, col. 1 on page 377, the unmodified circuit in Fig. 12 uses a rate of 200 ml/min which is less than 300. Also, paragraph 2, col. 1, page 377 discloses using a rate of 200 ml/min):

In reference to claim 17, Roberts discloses that the chamber is capable of mixing and heating the dialysate (Fig. 7 and 12, specifically Fig. 12 discloses a heater).

In reference to claim 18, Treu discloses that the chamber (88) is coupled to the fluid loop via a fluid supply path (Fig. 2 discloses that the chamber is coupled to the fluid supply path as the fluid enters 88 after it passes through 78).

In reference to claim 19, Roberts discloses that the feed rate and the discharge rate are less than the circulation rate (paragraph 2, col. 1, page 377 discloses using inflow and outflow rates of 30 ml/min while using a higher circulation rate. Also see paragraph 2, col. 2 of page 374 which discloses the same author cited as using a circulation rate of 200 ml/min and inflow and outflow rates of 36 ml/min thus allowing the fluid in the peritoneum to circulate several times before being discharged).

In reference to claim 20, Treu discloses that the chamber is directly coupled to the fluid loop (Fig. 2 discloses that 88 is directly coupled to the fluid loop 10).

In reference to claim 22, Roberts discloses that the dialysate is continuously fled, circulated and drained over a treatment period of about 8 hours or less (paragraph 2, col. 1, page 377 discloses the fluid circuit referenced in claim 1, which is based off of the circuit in the paragraph above, which teaches an 8 hour treatment).

In reference to claim 23, Treu discloses that the chamber can be adapted to accommodate a variable increase in the dialysate during treatment (Fig. 2, 88 allows a variable increase which is monitored by 90).

Claims 24-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Treu et al. (US Patent No. 6254567) in view of Roberts et al. ("Innovative Peritoneal Dialysis: Flow-Thru and Dialysate Regeneration"). Treu discloses the device substantially as claimed including a system for providing peritoneal dialysis to a patient (Fig. 2), the system comprising: a catheter having an inflow lumen and an outflow lumen

(col. 6, lines 3-6 disclose that a dual lumen catheter may be used) in communication with the patient's peritoneal cavity (20); and a fluid circuit (Fig. 2) in fluid communication with the catheter, the fluid circuit consisting of: a fluid loop (10), the fluid loop configured to circulate dialysate into, through and out of a peritoneal cavity of the patient (the dialysate follows the path through the loop 10 multiple times as it is regenerated); a supply of dialysate coupled to the fluid loop; a cycler (12) that pumps the dialysate into the fluid circuit at a feed rate and circulates the dialysate at a circulation rate along the fluid loop to remove a therapeutic effective amount of solutes and excess water from the patient (please note that the claim language does not require that the feed rate and circulation rates be specific rates as compared to other rates in the claim); a cleaning device (22) coupled to the fluid loop via a cleaning fluid path (the path includes entering the cleaning device via 32, flowing through the cleaning device and re-entering the fluid loop via 34) wherein the dialysate can be fed into the cleaning fluid path and cleaned at a cleaning rate prior to reintroduction into the fluid loop (please note that the claim language does not require that the cleaning rate be a specific rate relative to any other rate claimed, therefore the rate at which the fluid flows through the cleaning device is being interpreted as the cleaning rate); and a discharge fluid path (fluid path leading to 46) coupled to the fluid loop through which the dialysate is drained from the fluid circuit at a discharge rate. Treu, however, discloses components which are not claimed: pressure sensors (76 and 78) and valves 80 and 92. Treu later discloses, however, that other arrangements can be used such that inline pressure sensors are not necessary (col. 10, lines 11-12 and 20-21). Also, Treu further discloses that valves 80 and 92 as

well as the pressure sensors 76 and 78 are part of the cycler (col. 6, lines 33-35 and 42-45), and Applicant's specification discloses that a cycler can include other elements besides just a pump, such as valves, for example (Applicant's specification paragraph [0021]). Therefore, the pressure sensors and valves can be interpreted as part of the cycler, which is an element claimed by Applicant in each independent claims. Treu, however, does not disclose that the fluid is drained at a discharge rate that is less than the circulation rate allowing the dialysate to be circulated a plurality of times along the fluid loop prior to discharge. Roberts, however, discloses a similar fluid loop in which the fluid is drained at a rate less than the circulation rate thus allowing the fluid to circulate a plurality of times along the fluid loop prior to being drained (col. 1, second paragraph on page 377 discloses that the inflow and outflow of dialysate are set to equal each other, at a rate of 30 ml/min and that the fluid in the peritoneum is at a higher circulation rate; also see paragraph 2, col. 2 of page 374 which discloses the same author cited as using circulation rate of 200 ml/min and inflow and outflow rates of 36 ml/min thus allowing the fluid in the peritoneum to circulate several times before being discharged.). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Treu such that the pressure sensors are not used in the fluid circuit, as taught by Treu, and modify Treu with the lower discharge rate as taught by Roberts, in order to allow the fluid to be used the maximum amount possible before being drained as waste. Also it is the examiner's position that it would be obvious to use the teaching by Roberts to drain the fluid at a rate that is slower than the circulation rate, as this is only a change to the rates at which the system/fluid flow is

operated, and constitutes only finding an optimum value of a result effective variable which is routine in the art.

In reference to claim 25, Treu discloses that the fluid loop is coupled to the supply of dialysate, the cleaning fluid path and the discharge fluid path via a cycler (12).

In reference to claim 26, Treu discloses that the cycler includes a fluid circuit coupled to a pumping mechanism and a plurality of valves such that the cycler is capable of automatically controlling the flow of dialysate into and out of the fluid loop during treatment (Fig. 2 discloses valves 80 and 92).

In reference to claims, 27 and 28, Roberts discloses that the cleaning device contains a sorbent material (Fig. 6 discloses using a sorbent cartridge) capable of non\-selective removal of solutes from the dialysate prior to reuse and that the sorbent material is carbon (col. 1, paragraph 3, line 1).

In reference to claim 29, Treu discloses that the cleaning device contains an ion exchange resin (col. 1, line 24).

In reference to claim 30, Treu discloses the cleaning device contains a sorbent material capable of selective removal of solutes from the dialysate (col. 4, line 65).

Claims 3, 4 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Treu in view of Roberts et al. ("Innovative Peritoneal Dialysis: Flow-Thru and Dialysate Regeneration"). Treu in view of Roberts discloses the device substantially as claimed .including the feed rate and the discharge rates being lower than the circulation

rate (Other rate examples, though not meeting the limitations claimed include: col. 1, second paragraph on page 377 discloses that the inflow and outflow of dialysate are set to equal each other, at a rate of 30 ml/min and that the fluid in the peritoneum is at a higher circulation rate; also see paragraph 2, col. 2 of page 374 which discloses the same author cited as using circulation rate of 200 ml/min and inflow and outflow rates of 36 ml/min thus allowing the fluid in the peritoneum to circulate several times before being discharged. These rates of 200 and 36 are from the same researcher (Kraus et al.) that is being quoted in the second paragraph of col. 1, page 377). Roberts further discloses the feed/discharge rate being 50% of the circulation rate (Table 1 of Roberts discloses a peritoneal flow rate of 67ml/min and a clearance rate of 34 ml/min which makes the feed/discharge rate about 50% of the circulation rate). Roberts however, does not disclose that the feed and discharge rates are maintained equally at a rate that is one-third of the circulation rate, such that the dialysate circulates three times along the fluid loop or that the fluid is circulated around the loop a number of times equal to the feed rate divided by a difference between the circulation rate and the discharge rate. However, it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Roberts such that the feed and discharge rates are either one-half or one-third the circulation rate, because it is a mere manipulation or arithmetic in order to derive a circulation of two or three times around the loop, and because it has been held that discovering an optimum value of a result effective Variable involves only routine skill in the art. In re Boesch, 617 F.2d 272,205 USPQ 215 (CCPA 1980).

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Treu in view of Roberts et al. ("Innovative Peritoneal Dialysis: Flow-Thru and Dialysate Regeneration"). Treu discloses the device substantially as claimed except for the dialysate being contained in four separate containers each having a capacity of about 6 liters or less. Roberts, however, discloses two different dialysis set ups in which there are multiple containers each with a capacity of 6L or less (Fig. 1 and Fig. 3). While these setups do not disclose four dialysate containers, it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Treu in view of Roberts with extra dialysate containers, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art and it allows the therapy to be customized to the patient depending on how much dialysate is needed for each individual case. St. Regis Paper Co. v. Bemis Co., 193 USPQ 8.

Response to Arguments

Applicant's arguments filed 2/11/2009 have been fully considered but they are not persuasive. As presented in the rejections above, it is still the examiner's position that the phrase "consisting of" is new matter as the phrase requires that that the invention have only the elements listed after the phrase in the claim. Upon reviewing Applicant's arguments that Fig. 3a and paragraphs [0080]-[0082] and [0088]-[0091] provide support for such a claimed embodiment, it is the examiner's position that both the Fig. 3a and paragraphs disclose elements that are not claimed, such as a second

pump/cycler (44), a variable volume chamber (49) and back pressure regulator (59). The examiner also notes that the claimed "discharge fluid path" is not present in either Fig. 3a or the paragraphs pointed to in the specification.

In response to Applicant's arguments that the Treu reference teaches more elements than are claimed, such as the pressure sensors and the valves, the examiner points to col. 6, lines 33-35 and 42-45 which disclose that the sensors and the valves are part of the cycler, and Applicant's specification in paragraph [0021] discloses that a cycler can be made of other elements in addition to just a pump, such as valves, etc. Therefore it is the examiner's position that the valves and sensors disclosed by Treu can be interpreted as part of the cycler, wherein the "cycler" is a claimed component in each of Applicant's independent claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA C. SCHELL whose telephone number is (571)272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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